



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

M

| | | | | |
|--|-------------|------------------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/945,258 | 08/31/2001 | Peter H. St. George-Hyslop | 1034/1H570US1 | 1969 |
| 7590 03/29/2004 | | | | |
| DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022 | | EXAMINER CARLSON, KAREN C | | |
| | | ART UNIT 1653 | | |
| | | PAPER NUMBER | | |

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,258

Applicant(s)

ST. GEORGE-HYSLOP ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/01; 10/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

This Office Action is in response to the paper filed December 8, 2003. Claims 1-9 and 12-16 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 10, 11, and 17-23 are currently under examination.

Priority is to September 1, 2000.

Withdrawal of Objections and Rejections

The objection to the disclosure for lack of sequence identifiers for database accession numbers is withdrawn.

The rejection of Claims 10 and 11 under 35 U.S.C. 102(a) as being anticipated by St. George-Hyslop et al. (USP 6,020,143; issued February 1, 2000) is withdrawn.

The rejection of Claims 10 and under 35 U.S.C. 102(e) as being anticipated by St. George-Hyslop et al. (USP 6,383,758; issued May 7, 2002; priority to January 9, 1998) is withdrawn.

The rejection of Claims 10 and 11 under 35 U.S.C. 102(e) as being anticipated by Curtis et al. (WO 01/85912, claiming priority to US Patent Application 09/568,942, filed May 5, 2000) is withdrawn.

Maintenance of Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1653

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 11, and new Claims 17-23 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,020,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 10, 11, and new Claims 17-23 are drawn to a method for identifying a compound that alters PAMP activity by combining PAMP, its substrate, and the compound and determining changes in PAMP activity. Patented Claim 1 is drawn to a method for identifying substances that affect the interaction of presenilin 1 interacting protein and presenilin. Presenilin interacting proteins include PAMP, as noted on page 21 of the instant specification. Presenilin is a substrate for PAMP, as noted on page 3 of the instant specification. Therefore, the instant claims are encompassed by the patented claims.

Claims 10, 11, and new Claims 17-23 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,383,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 10, 11, and new Claims 17-23 are drawn to a method for identifying a compound that alters PAMP activity by combining PAMP, its substrate, and the compound and determining changes in PAMP activity. Patented Claim 1 is drawn to a method for identifying substances that alter the interaction of presenilin binding protein and presenilin. As claimed, presenilin binding protein is not distinguished from PAMP. Presenilin is a substrate for PAMP, as noted on page 3 of the instant specification. Therefore, the instant claims are encompassed by the patented claims.

Applicants argue both double patenting rejections together. Applicants urge that Claim 10 refers to specific amino acid sequences which are not disclosed in '143. The '143 patent

Art Unit: 1653

claims comprise the broad claim language "presenilin interacting protein", which Applicants teach in the specification include PAMP (page 21 of the instant specification). PAMP binds presenilin; thus, it is a presenilin binding protein. Therefore, the patent claims encompass the instant claims, even if specific sequences are set forth.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, and new Claims 17-23 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term presenilin associated membrane protein is indefinite because this term has no functional limitations. Also, it is not clear how the method steps of claim 10 coincide with the preamble of claim 10, that is, it is not clear how a method of determining PAMP activity in the presence of a compound will result in a compound useful for treating neurological disorders.

Applicants urge that the instant amendments to Claim 10 overcome this rejection. The claims still do not recite a function; the term "activity" is not a function. It is not clear how a difference in PAMP activity correlates with a compound for the treatment of neuropsychiatric or neurodevelopmental diseases. More specifically, will an increase or a decrease in PAMP activity be indicative of a compound for the treatment of neuropsychiatric or neurodevelopmental diseases?

Art Unit: 1653

New Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11, and new Claims 17-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe PAMP proteins having at least 90% identity to SEQ ID NO: 14, 16, or 18 and have indefinite "activity". Thus, the claims lack written description.

No claims are allowed.

Art of Record

WO 00/60069, PCT application of Applicants, having priority to April 1, 1999, teaches the instant invention, including SEQ ID NO: 14, 16, and 18. However, this WO does not designate the US, and thus is not available as art under 35 USC 102(e).

Art Unit: 1653

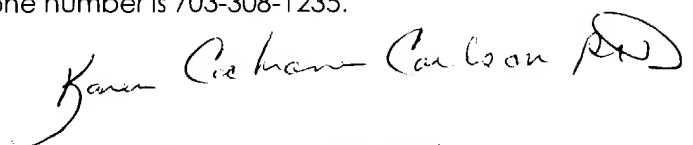
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER